

## REMARKS

This Response is submitted in reply to the Office Action mailed on October 29, 2008. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-706 on the account statement.

Claims 1-12, 14 and 15 are pending in the application. Claim 13 was previously canceled. Claims 6-8, 12, 14 and 15 were previously withdrawn from consideration. In the Office Action, Claims 1-5 and 9-11 remain rejected under 35 U.S.C. §103(a). In response, Applicants have amended Claims 1 and 9-11. The amendments do not add new matter and are supported in the specification (Preliminary Amendment filed February 16, 2006) at page 3, paragraph [0003] and page 5, paragraph [0020]. In view of the amendments and for at least the reasons provided below, Applicants respectfully submit that the obviousness rejection of Claims 1-5 and 9-11 should be withdrawn.

In the Office Action, Claims 1-5 and 9-11 remain rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2002/0107292 to Bortlik, et al. ("Bortlik"), in view of U.S. Patent No. 5,837,311 to Zelkha, et al. ("Zelkha"). Applicants submit that the cited references fail to disclose or suggest a natural lycopene concentrate that contains no solvent as required, in part, by amended independent Claims 1 and 9-11.

Conventional lycopene-containing preparations are obtained by extraction using a solvent. See, specification, paragraphs [0003-0006]. Due to this use of solvent as an aid in extraction, traces of solvent are thus likely to be found in the finished lycopene product. See, specification, paragraph [0003]. However, to provide a natural product, one must avoid using solvent to prevent the solvent extraction from modifying the native characteristics of the lycopene product. See, specification, paragraph [0007]. Therefore, a natural lycopene concentrate that contains no solvent by virtue of extraction from a lycopene-containing material without the use of a solvent is necessary in order to preserve the natural characteristics of the lycopene and thereby provide a concentrate with a high bioactivity. See, specification, page 5, paragraph [0020].

The natural lycopene concentrate is prepared, for example, by alkalinizing a lycopene-containing material under heat and isolating the lycopene from the fibers and other insoluble

compounds by solid-liquid separation. See, specification, paragraphs [0025-0027]. The lycopene-containing solution is then acid-precipitated from the filtrate and separated from carbohydrates and other soluble compounds by another solid-liquid separation step. See, specification, paragraphs [0037-0039]. A solvent is not necessary because the process for obtaining the lycopene concentrate is based on the pH-dependent “solubility” of lycopene from lycopene-containing materials such as tomato paste. By avoiding use of solvent as a means for extraction, Applicants have produced a natural lycopene product free of solvent in the finished product.

In contrast, the cited references teach lycopene or tomato products with at least traces of solvent in the finished product. For example, *Bortlik* teaches a composition in powder form that contains a combination of dissolved whey protein isolate and lycopene-containing oleoresin from LycoRed. This composition is mixed with acetone (solvent), which is subsequently “driven off” along with water to arrive at the finished product. See, *Bortlik*, paragraphs [0049-0051]. The Office Action cites the same teachings in *Bortlik* as support for the rejection. See, Office Action, page 3, lines 1-3. However, the teachings of *Bortlik* above clearly show the presence of solvent in the mixture. Though *Bortlik* states that the acetone is driven off, Applicants specification states, “lycopene-containing preparations ... are generally in the form of oleoresins and ... the lycopene is extracted with the aid of organic solvents; the solvents are therefore likely to be found in the form of traces in the finished product.” See, specification, page 3, paragraph [0003]. Therefore, even if *Bortlik* teaches the driving off acetone through moderate heating of the mixture of whey protein isolate, lycopene, water and acetone, it is very likely that solvent (acetone) traces or solvent residue will remain.

Even if the moderate heat drives off all the acetone added for extraction purposes, the lycopene-containing oleoresin from LycoRed also contains solvent residue. According to the material safety data sheet for Tomat-O-Red® 8% (attached as Exhibit A), which is the only oleoresin sold by LycoRed according to their website (see attached Exhibit B for printed webpage), the finished oleoresin product has trace amounts of solvent residue in the form of ethyl acetate. Therefore, even if moderate heating drives off the added extraction solvent (acetone), the solvent residue (ethyl acetate) already present in the LycoRed oleoresin would remain. *Bortlik* accordingly is deficient.

Contrary to the Office Action's assertions, *Zelkha* fails to remedy the deficiencies of *Bortlik*. Instead, *Zelkha* is directed to the use of a solvent to obtain a lycopene oleoresin. See, *Zelkha*, Abstract, lines 6-10. For example, the process of *Zelkha* comprises the step of subjecting a tomato pulp to solvent extraction in order to obtain an oleoresin containing lycopene. See, *Zelkha*, column 2, lines 28-40. In fact, *Zelkha* states that the lycopene oleoresin is "obtained by an appropriate choice of solvents" including ethyl acetate. See, *Zelkha*, column 4, lines 57-65; column 5, lines 14-16.

The Office Action asserts, however, that the patentability of a product does not depend on its method and that if the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Though this assertion may be true, it is rendered moot by Applicants present amendment of independent Claims 1 and 9-11 to recite the lycopene concentrate having no solvent. As such, the lack of solvent is an element of the product, not just the process and therefore distinguishes the claims from the prior art.

The Patent Office may allege, however, that *Zelkha* somehow remedies the deficiencies of *Bortlik* by teaching the complete removal of solvent and, as a result, a lycopene product with no solvent. This would be incorrect. In fact, the "Description" section of the material safety data sheet for Tomat-O-Red® 8% (Exhibit A), discussed above in regard to *Bortlik*, states, "Tomato extract containing 8% lycopene as well as other natural tomato phytonutrients (such as tocopherols, phytoene, phytofluene, beta-carotene, phospholipids and phytosterols) extracted from lycopene rich tomatoes and produced according to US patent No. 5,837,311," which is *Zelkha*. Simply stated, *Zelkha* teaches a process for producing the lycopene oleoresin used in *Bortlik*. That oleoresin has solvent residue. Therefore, because the data sheet for Tomat-O-Red® 8% discloses the presence of solvent residue in its finished product, and because Tomat-O-Red® 8% is produced according to the process taught in *Zelkha* (U.S. Patent No. 5,837,311), both *Zelkha* and *Bortlik* indeed teach the presence of solvent in its lycopene product. As such, *Zelkha* fails to remedy the deficiencies of *Bortlik*.

Applicants accordingly respectfully request that the rejection of Claims 1-5 and 9-11 under 35 U.S.C. §103(a) to *Bortlik* in view of *Zelkha* be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY

Robert M. Barrett  
Reg. No. 46,541  
Customer No. 29157

Dated: January 28, 2009

# **EXHIBIT A**

	<p>LycoRed Ltd. Hebron Road, Industrial Zone P.O.Box 320, Beer-Sheva 84102 Israel Tel: ++972 8 6296994, Fax: ++972 8 6236310 <a href="http://www.lycored.com">www.lycored.com</a> <a href="mailto:info@lycored.com">info@lycored.com</a></p>		
Subject:	DATA SHEET	Version : 07	Date: Dec 26 <sup>th</sup> , 2007
Product:	<b>Tomat-O-Red® 8%</b>	Catalogue no: 400033, 400034, 400035	Page 1 of 1

<b>Description</b>	Tomato extract containing 8% lycopene as well as other natural tomato phytonutrients (such as tocopherols, phytoene, phytofluene, beta-carotene, phospholipids and phytosterols) extracted from lycopene rich tomatoes and produced according to US patent No. 5,837,311 and EU patent No. 844,831.
<b>Origin</b>	Selected, non GMO, ripe tomatoes, specially bred for high lycopene content.
<b>Appearance</b>	Viscous, dark red liquid.
<b>Odor</b>	Characteristic.
<b>Applications</b>	A source of lycopene and natural color to be used in food, dietary supplements and cosmetic products.
<b>Certifications</b>	Produced according to ISO 9001:2000 standard and Israeli GMP regulations, non GMO.
<b>Regulatory Status</b>	Generally Recognized As Safe (GRAS) and as a color additive in the United States. Approved as food color E-160d and for use in dietary supplements in EC. Approved as food colorant for use in dietary supplements and for food fortification in Japan.
<b>Kosher</b>	Tomat-O-Red® 8% has been certified Kosher by the Orthodox Union (OU).
<b>Halal</b>	Tomat-O-Red® 8% has been certified Halal.
<b>Stability &amp; Storage</b>	Stable for five years from production date when stored in sealed original container at room temperature. Once opened, the Tomat-O-Red® 8% should be kept until it is used in a closed container at 4°C.

<b>Chemical &amp; Physical Analysis</b>		<b>Microbial Evaluation</b>	
Lycopene	> 8.0% (Spectrophotometrical Method)	Total plate count	Less than 1,000/gr
Water	< 0.5%	E. Coli	Negative in 10 gr
Solvent residue	< 50 ppm ethyl acetate (Head Space Method)	Salmonella	Negative in 10 gr
Heavy metals	< 10 ppm (ICP Analysis)	Ps. aeroginosa	Negative in 10 gr
Lead	≤ 1 ppm (ICP Analysis)	Staph. aureus	Negative in 10 gr
Arsenic	≤ 1 ppm (ICP Analysis)	Yeasts/Molds	Less than 100/gr
Mercury	≤ 1 ppm (ICP Analysis)		
Cadmium	≤ 1 ppm (ICP Analysis)		

<b>Packaging</b>	1kg & 10 kg in aluminum bottle 25 kg steel drums with food grade coating.
<b>Country of origin</b>	Israel
<b>Labeling</b>	Tomato extract containing lycopene

# **EXHIBIT B**



# LYCORED Creating Innovative Nutrition

**Fortified  
near  
water  
from**

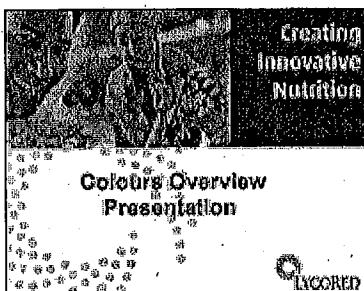
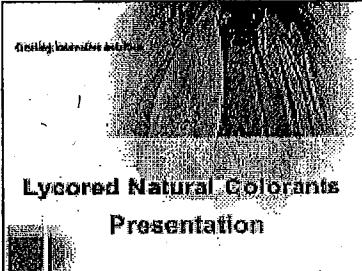
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Carotenoids || Microencapsulated Ing. || Special Ing. || Nutritional Ing. || Colorants || Branded Ing.

## Oleoresin

Tomat-O-Red® 8% is a natural tomato lycopene oleoresin designed for color compounders. The oleoresin can be used to produce colors ranging from yellow to red. Please contact us for technical assistance.

■ Tomat-O-Red® 8%



Lycopene	Lutein	Beta Carotene	Alpha Carotene	Astaxanthin	Zeaxanthin	Tocotrienols	L-Carnitine
Vitamins	Minerals	Other Ingredients	Vitamin B12	Vitamin D	Vitamin K	DHA	Amino Acids
Tomat-O-Red	CWD	Dispersion	Oleoresin	Lyc-O-Mato	Premixes	Cosmeceutical	

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